

MAY - 1 2012

510K SUMMARY

510K Number: k111927
Submitted By: Psychemedics Corporation
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Submission Contact: Virginia Hill

Date Prepared: April 25, 2012

Device Trade Name: Psychemedics Microplate EIA for Methamphetamine in Hair

Predicate Device: Psychemedics Methamphetamine and MDMA Assay, k011185

Product Code: DKZ

Device Classification/Name: 21 CFR 862.3100, Enzyme Immunoassay, Methamphetamine and Methamphetamine Metabolites; Classification II;

Intended Use: The Psychemedics Microplate EIA for Methamphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of methamphetamine in human head and body hair samples using a methamphetamine calibrator at 5 ng/10 mg hair cutoff for the purpose of identifying methamphetamine use. This product is intended exclusively for in-house professional use only and is not for sale to anyone.

The Psychemedics Microplate EIA for Methamphetamine in Hair provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgment must be applied to the interpretation of any drug-of-abuse test result.

Assay Description: The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Methamphetamine. The drug is recovered from the hair using a patented method (U.S. Patent #8,084,215). The screening portion of the test system consists of (1) microplate wells coated with multiple drugs including methamphetamine conjugated to bovine serum albumin (BSA) (patent pending), polyclonal sheep anti-methamphetamine, rabbit anti-goat secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to acidify the final reaction, and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.

Sample Collection:

A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair sample crimped within the foil is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory.

Materials required:

Hair sample collection kit, Microplate EIA for Methamphetamine, Microplate washer and reader, LC/MS/MS for confirmation.

Comparison of Psychomedics Microplate EIA for Methamphetamine with Psychomedics RIA Assay for Methamphetamine/MDMA

Item	Device	Predicate
Indications for Use	<p>The Psychomedics Microplate EIA for Methamphetamine is an enzyme immunoassay (EIA) for the preliminary qualitative detection of methamphetamine in human head and body hair samples using a methamphetamine calibrator at 5 ng /10 mg hair cutoff for the purpose of identifying methamphetamine use. This product is intended exclusively for in-house professional use only and not for sale to anyone. The test is not intended for over the counter sale to non-professionals.</p> <p>The Psychomedics Microplate EIA for Methamphetamine in Hair provides only a preliminary analytical test result. To confirm a presumptive screen positive result, a more specific alternate chemical method such as LC/MS/MS (liquid chromatography/mass spectrometry/mass spectrometry) must be used. Clinical consideration and professional judgment must be applied to the interpretation of any drug-of-abuse test result.</p>	<p>The Psychomedics Methamphetamine and MDMA assay is a radioimmunoassay (RIA) for the preliminary detection of d-methamphetamine, d,l-MDMA and metabolites in human hair samples using a 5 ng/10 mg hair cutoff for the purpose of identifying methamphetamine or MDMA (ecstasy) use. For a quantitative analytical results or to confirm positive results <i>via</i> the presence of the methamphetamine, MDMA and metbaolites, a more specific alternate chemical method must be used in order to obtain a confirmed analytical result.</p>
510k	K111927	K011185
Measurand	Methamphetamine	Methamphetamine
Matrix	Human head or body hair	Human head or body hair
Cutoff concentration	5 ng methamphetamine/10 mg hair	5 ng methamphetamine/10 mg hair
Type of Test	Enzyme Immunoassay	Radioimmunoassay
Method of	Microplate reader	Microplate reader

Measurement		
Extraction Method	Nonproteolytic Digestion	Proteolytic Digestion
Confirmation Method	LC/MS/MS	LC/MS/MS

Summary of Performance Testing

Precision Studies

Summary -Intra-Assay			Summary-Inter-Assay		
LEVEL	NEG	POS	LEVEL	NEG	POS
B₀ (-100%)	15	0	B₀ (-100%)	75	0
-75%	15	0	-75%	75	0
-50%	15	0	-50%	75	0
-25%	15	0	-25%	75	0
plus 25%	0	15	plus 25%	0	75
plus 50%	0	15	plus 50%	0	75
plus 75%	0	15	plus 75%	0	75
plus 100%	0	15	plus 100%	0	75

Agreement Testing

Five-hundred-thirty-six hair samples were assayed by the predicate device and by the Psychemedics Methamphetamine EIA. The discordance between EIA and RIA was < 0.2%. Sixteen percent of the total samples in the studies were body hair samples.

	Negative by Predicate	Positive by Predicate
EIA Positive	0	103
EIA Negative	428	5

Two-hundred thirteen of the samples were confirmed by LC/MS/MS, with the results shown in the following table.

LC/MS/MS:	0	≥ -50% of Cutoff & < Cutoff	≥ Cutoff, And < +50% of Cutoff	≥ +50% of Cutoff & < +100% of Cutoff	≥ +100% of cutoff
EIA Positive	0	9	8	8	78
EIA Negative	105	3	0	2	0

Samples vary in the amount of contamination on the surface; in fact, contamination is, by its very nature, random in the way in which it may present on the hair sample. Therefore, it is not surprising that a sample might be positive in one screening assay and not in the next, even if the assays are the same technology. The samples were negative by LC/MS/MS, demonstrating that the EIA negative results, although discordant with the predicate, are correct.

Cosmetic Treatment Study

Twenty methamphetamine-negative hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences were observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments.

Twelve methamphetamine-positive hair samples were treated with bleach, 12 with permanent wave, 12 with dye, 12 with relaxer, and 12 with shampoo, and the results compared to the same samples without the treatments. In each case of the 12 samples treated with a type of cosmetic treatment, 6 samples were treated with one brand of a particular product and 6 other samples with a second brand. The means and ranges of the EIA results of the 12 samples before and after the cosmetic treatments are shown in the table below. No positive samples became negative after cosmetic treatment.

Treatment Status	Bleach	Dye	Perm	Relaxer	Shampoo
	Mean (Range) of B/B ₀ x 100 Values of 12 Methamphetamine-Positive Samples in Methamphetamine EIA				
Before	21.1 (6.6 – 55.5)	22.1 (6.6 – 45.0)	22.1 (6.6 – 55.5)	21.3 (10.3 – 55.5)	24.9 (6.6 – 55.5)
After	25.0 (6.1 – 56.2)	25.7 (7.4 – 50.9)	36.3 (13.4 – 57.8)	32.4 (10.2 – 67.4)	26.3 (7.6 – 52.9)

Contamination Study

Potential environmental contamination of samples that are identified as presumptive positive in the screening assay is addressed by an extensive washing procedure prior to confirmation and application of a wash criterion following confirmation, as described below.

Contamination of hair by soaking in 1000 ng methamphetamine /mL of water resulted in a range of methamphetamine on the hair of 38.6 to 98.7 ng of methamphetamine /10 mg hair before washing. After washing by the procedure described below, the amount of methamphetamine remaining on the hair samples ranged from 1.1 to 3.0 ng/10 mg hair, with no samples at or above the cutoff even before application of the wash criterion.

Contamination of hair by soaking in 1000 ng methamphetamine /mL of saline resulted in a range of methamphetamine on the hair of 8.5 to 29.3 ng of methamphetamine /10 mg hair before washing. After washing by the procedure described below, the amount of methamphetamine remaining on the hair samples ranged from 0.2 to 1.0 ng/10 mg hair, with all samples negative (i.e., below the cutoff) even without application of the wash criterion.

The Wash Procedure

- a. Wash by Psychomedics' standard wash procedure:
 - i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove isopropanol.
 - ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0, with 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
 - iii. Repeat Step ii. two more times
 - iv. Add 2 mL of Wash Buffer and shake in waterbath for 60 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
 - v. Repeat Step iv. one more time
 - vi. Save wash from Step v.
- b. Analyze the last wash for methamphetamine.

Confirmation and Interpretation

- a. Perform confirmation procedures for methamphetamine, MDMA, MDEA, amphetamine.
- b. Calculate wash criterion:
 - i. Multiply the last wash value by 3.5.
 - ii. Subtract the value of the drug in the last wash from the value of the drug in the digested hair.
 - iii. If the result is less than the cutoff for the drug in the hair, the sample is interpreted as contaminated. If the result is \geq the parent drug cutoff, the sample is interpreted as positive due to ingestion. The parent-drug cutoff value for methamphetamine, MDMA or MDEA is 5 ng/10 mg hair.

Cross-reactivity and Interference Studies

Five compounds, shown in the table below, showed cross-reactivity in the Methamphetamine EIA assay. Sixty-seven other compounds showed no cross-reactivity in the assay. One-hundred-twenty-eight compounds tested for interference at $\pm 50\%$ of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Opiates EIA

Compound	Amount of Compound required to Produce a positive test at the cutoff of 5 ng methamphetamine/10 mg hair	Percent Cross-reactivity*
MDMA	5	100
MDEA	10	50
L-methamphetamine	29	17
PMA	80	6.2
PMMA	6	83.3

Stability of Calibrator and Control Solutions

The methamphetamine calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability of methamphetamine in methanol in the presence of other drugs of abuse was shown to exceed 1 year.

Recovery Study

Recovery of methamphetamine from hair of methamphetamine users was shown to be substantially equivalent to that of the predicate device.

Conclusion:

The Psychomedics Microplate EIA for Methamphetamine in Hair is substantially equivalent to the predicate device k011185, and the results are substantially equivalent to LC/MS/MS results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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MAY - 1 2012

Re: k111927
Trade/Device Name: Psychomedics Microplate EIA for Methamphetamine in Hair
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: LAF
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

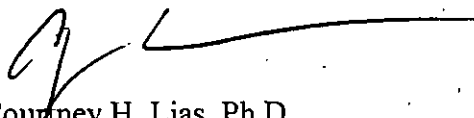
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number : k111927

Device Name: Psychemedics Microplate EIA for Methamphetamine in Hair

Indications For Use:

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Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k111927